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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,699	04/21/2004	Karen M. Cheves	1001.1705101	5388

28075 7590 07/03/2008
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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,699	Applicant(s) CHEVES ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/31/2008 has been entered.

Acknowledgements

2. This office action is in response to the reply filed 3/31/2008.
3. Claim 25 was cancelled. Claims 4 and 15 was amended.
4. Thus, claims 4 and 15 are pending for examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Grayzel et al (6942680). Grayzel et al discloses a cutting balloon catheter (10), comprising: an elongate catheter shaft (54); a balloon (14) coupled to the shaft, the balloon having a

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first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (col 4, Ins 1-6); a cutting blade (16) for severing or breaking up a lesion affixed to the balloon (col 3, Ins 59-64; col 4, Ins 12-22; col 6, Ins 54-55, 61-65; col 7, Ins 28-31), the cutting blade including means for cutting and means for gripping thereon and having a longitudinal axis (col 3, Ins 59-64; col 4, Ins 12-22; col 6, Ins 54-55, 61-65; col 7, Ins 28-31); wherein the means for cutting and means for gripping are defined by a series of undulations (16) on the cutting blade; and wherein the undulations curve from side-to-side relative to the longitudinal axis (16; col 10; Figs 6a-10g).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel et al (6942680) in view of Lary (6306151). Grayzel discloses the invention substantially as claimed except for disclosing that the elongate shaft has a second lumen. Lary teaches that it is known to have an elongate shaft having a second lumen (17, 19) for the purpose of having separate lumens for a guidewire and to inflate/deflate the balloon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the elongate shaft as taught by Grayzel with the second

lumen as taught by Lary for the purpose of having separate lumens for a guidewire and to inflate/deflate the balloon.

9. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al (5320634) in view of Parodi (5250070).

10. Vigil et al discloses a medical device, comprising: an elongate shaft (14) having a proximal end, a distal end, a first lumen (14) extending therethrough, and a second lumen (col 4, lns 63-64) extending therethrough; a balloon (12) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 3b); and one or more cutting members affixed to the balloon (31), the one or more cutting members for severing or breaking up a lesion each having a longitudinal axis (Figs 3a, 4a-b), wherein the one or more cutting members each include a traction region that is configured to improve traction between the balloon and a target site (Figs 3a, 4a-b; and previous discussion of "traction region" in paragraphs 4-7 of the Final office action mailed on 11/1/2006). In reference to claim 15, Vigil et al additionally discloses a cutting blade (31) affixed to the balloon (Fig 3a-b, 4a-b), the cutting blade including means for cutting and means for gripping thereon and having a longitudinal axis (Fig 3a-b, 4a-b).

11. However, Vigil et al fails to expressly disclose wherein the cutting member/blade has a traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis.

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12. Parodi teaches that it is known to have the traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis (Fig 6c, summary, col 3, Ins 2-col 4, Ins 11) for the purpose of providing a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, Ins 3-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the traction region as taught by Vigil et al with the traction region defined by a series of undulations curving from side to side relative to the longitudinal axis in the cutting members as taught by Parodi for the purpose of a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, Ins 3-11). Additionally, see Response to Arguments below.

Response to Arguments

13. Applicant's arguments filed 3/31/2008 have been fully considered but they are not persuasive.

14. The Applicant argues that:

- i. Parodi does not teach a cutting member or cutting blade for severing or breaking up a lesion. Parodi teaches features that are designed to reduce damage and/or cutting. The teachings cannot be applied to a cutting member/black for severing or breaking up a lesion (Remarks, pg 5)

15. In response to the Applicant's arguments (i), the Examiner notes that Parodi teaches that the undulating cutting members (Fig 6c) contact only a small part of the

endothelium during angioplasty dilatation. Thus, in comparison to prior art balloons that contact the entire endothelium (Fig 5b) and flatten and destroy nearly all of the endothelium (Fig 5b) during angioplasty dilatation the ribs structured cutting members (6, Fig 6c) contact only 10% of the endothelium and only a small part of the endothelium (Fig 5c) is flattened and destroyed. These teachings of Parodi clearly indicate that the ribs (7) are structured to cut and break up lesions during angioplasty dilatation treatment as shown in Fig 5c. The teachings of Parodi can be properly applied to the cutting members of Vigil et al and the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761